REMARKS

Claims 41-66 are pending in this application. Currently claims 41, 42, 45 and 46 are under consideration by the Examiner for prosecution purposes of this application. By this Amendment, claim 41 has been amended and the remaining claims are unchanged..

Claim 41 has been amended in the interest of expediting prosecution, i.e., to obviate the § 112, first paragraph (enablement) rejection, and not for reasons related to patentability. In addition, the amendment to claim 41 puts the claim in better form for Appeal purposes. Claim 41 c) has been amended to include that the claimed "said" fragment is a biologically active fragment. Support for this amendment can be found throughout the specification, for example at page 54, line 14 to page 55, line 1. Claim 41 (d) has been amended to include that the claimed immunogenic fragments are used to make an antibody which specifically binds to an isolated polypeptide selected from the group consisting of a), b) and c) of claim 41. Support for this amendment can be found throughout the specification, for example at page 10, lines 3-6, and originally filed claim 13 of the grand-parent application 08/884,072, now U.S. Patent 5,872,234.

Allowable Subject Matter

Applicants acknowledge that the Examiner has stated at page 3 of this Office Action that claims 42 and 46 contain allowable subject matter.

Rejoinder of Claims

Applicants continue to request the rejoinder of claims 43, 44 and 47-50 directed to methods of producing the claimed polypeptides and of using the claimed polypeptides upon allowance of a product claim per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103 (b)" which sets forth the rules that upon allowance of any of the product claims, the process claims covering the same scope as the allowed product claim(s) are to be rejoined.

Rejection under 35 U.S.C. §112, first paragraph (enablement)

Claims 41 and 45 stand rejected under the first paragraph of 35 U.S.C. §112 because allegedly the Specification does not reasonably provide enablement for the recited immunogenic fragments of SEQ ID NO:1 for the reasons asserted at pages 2 and 3 of this Office Action.

To fulfill the enablement requirement of 35 U.S.C. §112, first paragraph, the claimed invention must be described in the specification in such as way as to enable one skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is submitted that the Specification does reasonably provide an adequate written description to **enable** the immunogenic fragments of SEQ ID NO:1 as "now" claimed at the time of the filing of this application.

The Examiner is well aware that the relative skill of those in the art is very high and the amount of direction or guidance needed to be disclosed in the Specification to make or use the immunogenic fragments of SEQ ID NO:1 as "now" claimed is minimal. As mentioned in the prior Reply, the immunogenic fragments of the claimed polypeptide are described in the specification in such a way as to enable one skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification, at page 8, lines 25 and 26, teaches that the immunogenic fragments of ECMP are preferably about 5 to about 15 amino acids in length. Furthermore, at page 55, Example XI, the Specification specifically teaches how to produce ECMP-1 specific antibodies. This approach is confirmed in the Nakamura, T. *et al.* reference, which made antibodies to DANCE using a "KLH-conjugated polypeptide CMTRPIKGPRDIQLDLE MITVN, which corresponds to amino acids 406-426 of mouse and rat DANCE protein" (page 22477, column 1). Applicants submit and the Examiner seems to concur that the Specification is enabling as to the making of antibodies that specifically binds to a polypeptide of claim 41 a) and/or b) and/or a biologically active fragment of claim 41 c) using the recited immunogenic fragments.

Instead the Examiner bases this rejection on the alleged failure of the Specification to provide an enabling disclosure as to the use of the immunogenic fragments and the antibodies made to these immunogenic fragments. The claimed immunogenic fragments as recited in claim 41 d) are used to make an antibody that specifically binds to a polypeptide of claim 41 a) and/or b) and/or a biologically active fragment of claim 41 c). The antibody so produced can be used in protein expression monitoring systems of a polypeptide of claim 41 a) and/or b) and/or a biologically active fragment of claim 41 c),

e.g., Western Blots (*see*, for example, .the Nakamura, T. *et al.* reference, pp. 22481 and 22482, "Recombinant Expression of DANCE Protein"). The antibody so produced can also be used to purify the polypeptide as recited in claim 41 (*see*, for example, Example XII, "Purification of Naturally Occurring ECMP Using Specific Antibodies").

In addition, as set forth in *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971):

> The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.
>
> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Contrary to the standard set forth in *Marzocchi*, the Office Action has failed to provide any ***reasons*** why one would doubt that the guidance provided by the present Specification would enable one to make and use the recited immunogenic fragments of SEQ ID NO:1. Hence, a *prima facie* case for non-enablement has not been established with respect to the recited immunogenic fragments of SEQ ID NO:1.

Accordingly, for all the above reasons, the claimed subject matter is described in the Specification in such a way that one skilled in the art can make and/or use the claimed invention. Therefore, reconsideration and withdrawal of this rejection to the claims are respectfully requested.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejection. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney/Agent below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**, as set forth in the enclosed fee transmittal letter.

Respectfully submitted,
INCYTE CORPORATION

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VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS

Claim 41 has been amended as follows:

41. (Twice Amended) An isolated polypeptide selected from the group consisting of:

a) a polypeptide comprising an amino acid sequence of SEQ ID NO:1,

b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO:1, said polypeptide having extracellular matrix protein activity,

c) a biologically active fragment of a polypeptide having an amino acid sequence of SEQ ID NO:1, said biologically active fragment having extracellular matrix protein activity, and

d) an immunogenic fragment of a polypeptide consisting of at least 5 amino acids of the amino acid sequence of SEQ ID NO:1, said immunogenic fragment is used to make an antibody which specifically binds to an isolated polypeptide selected from the group consisting of a), b) and c).